

**H****Briefs and Other Related Documents**

United States Court of Appeals,  
 Federal Circuit.  
 NOVARTIS PHARMACEUTICALS  
 CORPORATION, Novartis AG, Novartis Pharma  
 AG,  
 and Novartis International Pharmaceutical Ltd.,  
 Plaintiffs-Appellants,  
 v.  
 ABBOTT LABORATORIES, Defendant-Cross  
 Appellant.  
 Nos. 03-1367, -1393.

July 8, 2004.  
 Rehearing and Rehearing En Banc Denied Aug. 31,  
 2004.

**Background:** Owner of patent for formulation of pharmaceutical drug cyclosporin sued competitor for infringement. The United States District Court for the District of Delaware, Joseph J. Farnan, Jr., J., 294 F.Supp.2d 557, granted judgment of noninfringement as matter of law, and owner appealed.

**Holding:** The Court of Appeals, Prost, Circuit Judge, held that patent, whose lipophilic component could include one or more surfactants so long as it also contained at least one non-surfactant lipophilic excipient, was not equivalently infringed by accused product whose only lipophilic component was surfactant.

Affirmed in part and reversed in part.


Bryson, Circuit Judge, dissented and filed opinion.

West Headnotes

**[1] Patents**  **226.6**  
291k226.6 Most Cited Cases

**[1] Patents**  **314(5)**  
291k314(5) Most Cited Cases

In determination of patent infringement, claims must be first construed by court, and then properly construed claims must be compared to accused product by fact finder.

**[2] Patents**  **324.5**  
291k324.5 Most Cited Cases

District court's patent claim construction is reviewed de novo.

**[3] Federal Courts**  **776**  
170Bk776 Most Cited Cases

District court's grant of motion for judgment as matter of law (JMOL) is reviewed de novo.  
Fed.Rules Civ.Proc.Rule 50, 28 U.S.C.A.


**[4] Courts**  **96(7)**  
106k96(7) Most Cited Cases

Law of regional circuit applies to issue of whether collateral estoppel applies in patent infringement case.

**[5] Judgment**  **713(1)**  
228k713(1) Most Cited Cases


**[5] Judgment**  **956(1)**  
228k956(1) Most Cited Cases

Party seeking to invoke collateral estoppel bears burden of showing: (1) previous determination was necessary to decision; (2) identical issue was previously litigated; (3) issue was actually decided in decision that was final, valid, and on merits; and (4) party being precluded from relitigating issue was adequately represented in previous action.

**[6] Patents**  **324.52**  
291k324.52 Most Cited Cases

Owner of pharmaceutical patents, who failed to appeal from jury's verdict that parent patent was not infringed, was not collaterally estopped from appealing trial court's construction of claim term found in both parent and daughter patents, which had formed basis for court's post-verdict judgment as matter of law (JMOL) that daughter patent was not infringed; it was unclear whether court's construction of term was necessary to jury's noninfringement decision.

**[7] Patents**  **162**  
291k162 Most Cited Cases

**[7] Patents**  **165(3)**  
291k165(3) Most Cited Cases

General presumption that words of patent claim have meaning that person of ordinary skill in relevant art

would ordinarily attribute to them may be rebutted when: (1) patentee has chosen to be his own lexicographer, or (2) claim term lacks such clarity that there is no means by which scope of claim may be ascertained from language used.

**[8] Patents** 🔑161

291k161 Most Cited Cases

If disputed patent claim term has no previous meaning to those of ordinary skill in prior art, its meaning must be found elsewhere in patent.

**[9] Patents** 🔑167(1)

291k167(1) Most Cited Cases

Most often, patent specification is single best guide to meaning of disputed claim term.

**[10] Patents** 🔑168(2.1)

291k168(2.1) Most Cited Cases

Construing court must examine prosecution history to determine whether patentee relinquished claim coverage by amendment or through argument to overcome or distinguish prior art reference.

**[11] Patents** 🔑159

291k159 Most Cited Cases

Although extrinsic evidence may be used by construing court to help understand disputed patent claim limitation, it may not be used to vary, contradict, expand, or limit claim language from how it is defined, even by implication, in specification or file history.

**[12] Patents** 🔑101(2)

291k101(2) Most Cited Cases

"Lipophilic phase component," called for in patent for formulation of pharmaceutical drug cyclosporin, could include surfactant, but could not be composed entirely of surfactants.

**[13] Patents** 🔑101(2)

291k101(2) Most Cited Cases

"Lipophilic phase component," called for in patent for formulation of pharmaceutical drug cyclosporin, did not have to be entirely immiscible with hydrophilic phase components in absence of surfactants.

**[14] Patents** 🔑251

291k251 Most Cited Cases

Patent for formulation of pharmaceutical drug cyclosporin, whose lipophilic component could include one or more surfactants so long as it also

contained at least one non-surfactant lipophilic excipient, was not equivalently infringed by accused product whose only lipophilic component was surfactant.

**[15] Patents** 🔑237

291k237 Most Cited Cases

Doctrine of equivalents may not be applied when accused product's substituted feature places it outside scope of recited claim element.

**[16] Patents** 🔑324.52

291k324.52 Most Cited Cases

Party who prevails on claim of patent noninfringement has no right to file "conditional" cross-appeal to introduce new argument or challenge claim construction, but may simply assert alternative grounds in record for affirming judgment.

**[17] Federal Courts** 🔑772

170Bk772 Most Cited Cases

It is only necessary and appropriate for appellee to file cross-appeal when it seeks to enlarge its own rights under judgment or to lessen rights of its adversary under judgment.

**Patents** 🔑328(2)

291k328(2) Most Cited Cases

5,342,625. Cited.

**Patents** 🔑328(2)

291k328(2) Most Cited Cases

6,007,840. Not Infringed.

\*1329 Robert L. Baechtold, Fitzpatrick, Cella, Harper & Scinto, of New York, NY, argued for plaintiffs-appellants. With him on the brief were Nicholas N. Kallas, Stevan J. Bosses, and Diego Scambia.

Jeffrey I. Weinberger, Munger, Tolles & Olson LLP, of Los Angeles, CA, argued for defendant-cross appellant. With him on the brief were Ted G. Dane and Andrea Weiss Jeffries.

Before BRYSON, GAJARSA, and PROST, Circuit Judges.

Opinion of the Court filed by Circuit Judge PROST. Dissenting opinion filed by Circuit Judge BRYSON.

PROST, Circuit Judge.

Appellants Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma \*1330 AG, and

Novartis International Pharmaceutical Ltd. (collectively "Novartis") appeal the claim construction and entry by the United States District Court for the District of Delaware of a judgment as a matter of law ("JMOL") for noninfringement of United States Patent No. 6,007,840 ("the '840 patent") in favor of Abbott Laboratories ("Abbott"). Novartis Pharms. Corp. v. Abbott Labs., Inc., 294 F.Supp.2d 557 (D.Del.2003). While we reverse the claim construction of "lipophilic component," we perceive no error in the district court's finding that no reasonable juror could conclude that an equivalent to a pharmaceutically acceptable non-surfactant lipophilic excipient, which is capable of dissolving cyclosporin, is present in Abbott's accused product. Accordingly, we affirm the grant of JMOL for noninfringement.

#### BACKGROUND

Novartis commenced a lawsuit against Abbott for allegedly infringing United States Patent No. 5,342,625 ("the '625 patent") and the '840 patent. The '625 and '840 patents relate to pharmaceutical compositions of the drug cyclosporin, which help prevent organ rejection in transplant patients. Cyclosporin is highly hydrophobic, and as a consequence, has been difficult to administer in a convenient form that provides the desired bioavailability to a patient. '840 patent, col. 3, l. 32, col. 4, ll. 32-40. The two patents asserted by Novartis are directed to compositions that facilitate human absorption of cyclosporin by use of a microemulsion. '625 patent, col. 5, ll. 1-5; '840 patent, col. 4, l. 64-col. 5, l. 1.

After the district court conducted a *Markman* hearing and construed the disputed terms in the '625 and the '840 patents, Novartis narrowed its allegation of infringement in its complaint to claim 1 of the '625 patent [FN1] and claim 81 of the '840 patent [FN2]. Each of the remaining asserted claims calls for a microemulsion pre-concentrate composition that, upon addition of water, forms an oil-in-water ("o/w") microemulsion. The parties disputed, among other things, whether Abbott's product includes a "lipophilic phase component" in the '625 patent or a "lipophilic component" in the '840 patent. In addition, the parties disputed whether "surfactant," as it is used in each of the asserted patents, encompasses \*1331 both hydrophilic and lipophilic surfactants.

FN1. Claim 1 reads as follows:

A pharmaceutical composition comprising a cyclosporin as active ingredient,  
1) a hydrophilic phase component

comprising

1.1) a pharmaceutically acceptable di- or partial-ether of the formula

$R_1-[O-(CH_2)_2]_x-OR_2$

wherein  $R_1$  is  $C_{1-5}$  alkyl or tetrahydrofurfuryl,  $R_2$  is hydrogen,  $C_{1-5}$  » » » » alkyl or tetrahydrofurfuryl, and  $x$  is an integer from 1 to 6, or

1.2) 1,2-propylene glycol;

2) a lipophilic phase component; and

3) a surfactant;

wherein said composition is a microemulsion pre-concentrate, which upon dilution with water to a ratio of 1:1 parts by weight pre-concentrate to water or more of said water, is capable of providing an oil-in-water microemulsion having average particle size of less than about 1,000.

FN2. Claim 81 reads as follows:

An oral pharmaceutical composition comprising  
about 5 to about 25% by weight of cyclosporin A, about 0.5 to about 90% by weight of a propylene glycol hydrophilic component, about 0.5 to about 90% by weight of a lipophilic component and about 0.5 to about 90% by weight of a hydrophilic surfactant, all weight percents being based on the total weight of the composition, the relative proportion of said cyclosporin A, hydrophilic component, lipophilic component and hydrophilic surfactant being such that upon dilution of said composition with adequate water, an oil-in-water microemulsion having an average particle size of less than about 1,500 is spontaneously formed.

In its claim construction of the phrase "lipophilic phase component," the district court held that the term requires:

at least one excipient meeting the following criteria: (1) a pharmaceutically acceptable lipophilic solvent in which cyclosporin is soluble, which is (2) immiscible with both water and the hydrophilic phase component(s) (in the absence of a surfactant), and which (3) lacks the amphiphilic function characteristic of a surfactant (i.e. it *must not be a surfactant* ).

Novartis, 294 F.Supp.2d at 561 (emphasis added).

The district court construed "surfactant" to encompass both hydrophilic and lipophilic surfactants. While Novartis disputes whether the claim construction of "lipophilic phase component" is

correct, the parties agree that this term bears the same meaning as the term "lipophilic component," as used in the '840 patent. [FN3]

FN3. For convenience, we will use the terms "lipophilic phase component" and "lipophilic component" interchangeably.

According to Abbott, its accused product, Gengraf, is a cyclosporin formulation that contains only hydrophilic excipients and surfactants. The accused product contains an ingredient called Span 80, which Abbott contends is a surfactant and not a "lipophilic component." After the parties put on their evidence, the district court permitted Novartis to submit to the jury the question of whether Abbott infringes either of the asserted patents under the doctrine of equivalents. The jury returned a verdict finding that Abbott did not infringe claim 1 of the '625 patent, but did infringe claim 81 of the '840 patent. Abbott moved for a judgment as a matter of law ("JMOL") in its favor on claim 81, or in the alternative, a new trial because the district court had erroneously excluded relevant evidence and because the '840 verdict is facially inconsistent with the '625 verdict and against the clear weight of evidence.

The district court granted Abbott's motion for a JMOL. *Id.* at 567. The court noted that under its claim construction, "the 'lipophilic phase component' cannot be a surfactant." *Id.* at 565; see also *id.* at 566 ("Under the Court's claim construction, Novartis is precluded from claiming that surfactants are the equivalent of the 'lipophilic phase component.'"). In construing the claims and concluding that surfactants cannot be a component of the lipophilic phase, the district court relied on a passage from the '625 specification, which states:

Suitable components for use as lipophilic phase include any pharmaceutically acceptable solvent which is non-miscible with the selected hydrophilic phase, e.g. as defined under (1.1.) or (1.2.). Such solvents will appropriately be devoid or substantially devoid of surfactant function.

'625 patent, col. 8, ll. 58-63. The court effectively read this language as a disavowal of any lipophilic component having surfactant function. In addition, the district court noted that the enumeration of three excipient components in the claim language gave support to viewing each component as separate and distinct. Lastly, the district court observed that the patentee had acknowledged during the prosecution of the application that led to the '840 patent that distinctions exist between surfactant and lipophilic compounds that differentiate the chemical entity of

each class of compound. According to the district court, "[b]ecause surfactants are expressly excluded from coverage, a surfactant acting as the 'lipophilic phase component'\*1332 is inconsistent with the language of the claim, as construed by the Court." *Novartis*, 294 F.Supp.2d at 567. Because Span 80 is a surfactant, the district court reasoned that Novartis could not, as a matter of law under the specific exclusion principle, establish that the substance is an equivalent to the "lipophilic component." *Id.* Accordingly, the district court concluded that Novartis could not demonstrate that Abbott infringes under the doctrine of equivalents. *Id.*

#### STANDARD OF REVIEW

[1][2][3] In a determination of infringement, the claims must be first construed by the court, and then the properly construed claims must be compared to the accused product by the fact finder. *Cybor Corp. v. FAS Techs. Inc.*, 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc). If challenged, we review claim construction de novo. *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1330 (Fed.Cir.2004); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). We likewise review the grant of a JMOL for noninfringement de novo, reapplying the JMOL standard used by the district court. *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1373 (Fed.Cir.2003); *Markman*, 52 F.3d at 975. "To prevail on a renewed motion for JMOL following a jury trial, a party 'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings.' " *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed.Cir.1998) (citing *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed.Cir.1984)); Fed.R.Civ.P. 50(b). If the former situation applies, "we must view the evidence in the light most favorable to the non-moving party, and determine whether the record contains the 'minimum quantum of evidence from which a jury might reasonably afford relief.' " *Glenn Distribs. Corp. v. Carlisle Plastics, Inc.*, 297 F.3d 294, 299 (3d Cir.2002) (quoting *Parkway Garage, Inc. v. City of Philadelphia*, 5 F.3d 685, 691 (3d Cir.1993)).

#### DISCUSSION

##### I. Collateral Estoppel

As a threshold issue, Abbott asserts that Novartis is barred in this appeal from challenging the jury verdict on the '625 patent or the JMOL on the '840 patent. Because the parties agree that the terms

"lipophilic component" and "surfactant" are common to the '625 and '840 patents, Abbott argues that Novartis' failure to challenge the construction of these terms in connection with the '625 patent estops Novartis from challenging their meaning in the related '840 patent. According to Abbott, "any legal determinations or factual findings necessary to the jury's verdict as to claim 1 of the '625 patent, the parent of the '840 patent, must be accorded preclusive effect." (Citing Mycogen Plant Science, Inc. v. Monsanto Co., 252 F.3d 1306, 1311 (Fed.Cir.2001)).

Novartis claims that it preserved its right to challenge the jury verdict on the '625 patent, and that collateral estoppel does not apply to preclude its challenge to the JMOL on the '840 patent. As evidence, Novartis notes that when discussing the construction of the term "surfactant," it pointed out that the correct construction of this term is relevant only to the '625 patent. Novartis further observes that it requested that "if this Court reverses the district court's claim construction" and "if this Court does not reinstate the jury [infringement] verdict," then "it is requested that ... the case [be] remanded for further proceedings consistent with the \*1333 proper construction of the claim terms." According to Novartis, the "further proceedings" necessarily include proceedings on claim 1 of the '625 patent as well as claim 81 of the '840 patent. Novartis moreover notes that Abbott admitted that the Notice of Appeal may be broad enough to encompass the appeal of the jury verdict on the '625 patent. In sum, Novartis asserts that (1) its conditional request of this court to construe a term for the '625 patent, (2) its request to remand "for further proceedings," and (3) Abbott's concession that the Notice of Appeal may be sufficiently broad to encompass an appeal of the '625 patent verdict, suffice to show that it preserved its right to challenge the claim construction, the noninfringement verdict on the '625 patent, and the JMOL that followed.

[4][5] We apply the law of the regional circuit to the issue of collateral estoppel in circumstances such as those presented here. RF Del., Inc. v. Pac. Keystone Techs., Inc., 326 F.3d 1255, 1261 (Fed.Cir.2003). The party seeking to invoke collateral estoppel bears the burden, Dici v. Pennsylvania, 91 F.3d 542, 548 (3d Cir.1996), of showing the following four elements are present: "(1) the previous determination was necessary to the decision; (2) the identical issue was previously litigated; (3) the issue was actually decided in a decision that was final, valid, and on the merits; and (4) the party being precluded from relitigating the issue was adequately represented in

the previous action." Hawksbill Sea Turtle v. FEMA, 126 F.3d 461, 475 (3d Cir.1997) (citing Raytech Corp. v. White, 54 F.3d 187, 190 (3d Cir.1995)).

Starting with Novartis' contention that its appeal of the jury verdict on the '625 patent was preserved, we note that Novartis, from the beginning, has maintained that "this is an appeal from entry of JMOL overturning a jury verdict finding Abbott guilty of infringement under the doctrine of equivalents." (Emphasis added). According to Novartis, "[t]he element at the core of this appeal (in that it formed the basis for the district court's grant of JMOL ) is the 'lipophilic component' element." (Emphasis added). As a consequence of the district court's allegedly erroneous claim construction, Novartis urged this court to "overturn the JMOL ruling " and reinstate the jury's verdict. (Emphasis added). Novartis urged that in the alternative, if this court decides against reinstating the verdict, but rather "orders a retrial, [this court] should construe the term 'surfactant' to provide guidance " to the district court. (Emphasis added). The purpose of examining the term "surfactant," therefore, is not to attack the '625 patent jury verdict, as Novartis belatedly now contends in response to Abbott's collateral estoppel argument, but rather to provide guidance to the district court if we order a retrial of the '840 patent case. In support of its proposed alternative, Novartis cited Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1366 (Fed.Cir.2003), as a parallel situation. There, this court consented to construe terms that *did not* form a part of the appealed summary judgment because they "may be relevant to the remand determination of infringement" and because they were found to be construed erroneously. *Id.* We find no language in Novartis' opening brief stating that this is also an appeal from the jury verdict on the '625 patent or arguments explaining why the allegedly erroneous claim construction compels us to conclude that the jury's noninfringement verdict on the '625 patent mandates a reversal. It is our understanding from Novartis' statement of its position that "this is an appeal from entry of JMOL" and that this court need not broach the meaning of "surfactant," which itself does not form a part of the appealed \*1334 JMOL, unless this court remands the case for a retrial. For reasons discussed below, we affirm the JMOL, and thus we find remand unwarranted. Based on our affirmance, our review of the term "surfactant," as it pertains to the '625 patent, is uncalled for.

[6] As to collateral estoppel, we find it inapplicable to the JMOL on the '840 patent. Here, the jury

determined that Novartis failed to prove by a preponderance of evidence that Abbott infringed the '625 patent under the doctrine of equivalents. The verdict form on which the jury indicated its decision did not require the jury to specify the one or more limitations in claim 1 that it found Abbott's product did not contain. Further, there is no record evidence explaining the jury's rationale for its verdict. Assuming that the district court's claim construction of "lipophilic component" was the dispositive element that proved necessary to the jury's noninfringement verdict, as Abbott urges, it would appear that the jury's infringement verdict on the '840 patent is quite possibly contradictory. One explanation may be as Novartis suggests. According to Novartis, the jury may have "include[d] all of the SPAN® 80 and CREMOPHOR® EL ingredients within the 'surfactant' component of the [625] claim, thereby leaving no ingredient to serve as the lipophilic component." Because claim 81 called more specifically for a hydrophilic surfactant, the jury could have concluded that Cremophor EL is the only surfactant that meets the hydrophilic surfactant element, leaving the jury free to conclude that the unaccounted for Span 80 was, based on testimony from Novartis' expert, not acting as a surfactant but rather as a lipophilic component in the claimed composition. In any event, we cannot conclude from the limited information available that the district court's construction of "lipophilic phase component," proved necessary to the jury's noninfringement decision on the '625 patent. Accordingly, Abbott has not met its burden to show that the claim construction of that term by the district court was necessary to the jury's noninfringement decision. Collateral estoppel therefore should not apply to preclude Novartis from challenging the claim construction and the JMOL in regards to the '840 patent.

## II. Claim Construction

[7] In construing claims, our analysis must begin and remain centered on the claim language itself. *Interactive Gift Express, Inc. v. Compuserve, Inc.* 256 F.3d 1323, 1331 (Fed.Cir.2001). We generally presume that the words of a patent claim have the meaning that a person of ordinary skill in the relevant art would ordinarily attribute to them. *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed.Cir.2002); *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed.Cir.1999). The presumption may be rebutted when: (1) the patentee has chosen to be his own lexicographer, or (2) a claim term lacks such clarity that there is "no means by which the scope of the claim may be ascertained from the language used." *Johnson Worldwide*, 175

F.3d at 990.

[8][9][10][11] If the disputed claim term "is a term with no previous meaning to those of ordinary skill in the prior art[,] its meaning, then, must be found [elsewhere] in the patent." *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1568 (Fed.Cir.1997). Most often, the specification "is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). Even when guidance is not provided in explicit definitional format, "the specification may define claim terms 'by implication' such that the meaning may be 'found in or ascertained by a reading of the patent documents.'" \*1335 *Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1268 (Fed.Cir.2001) (quoting *Vitronics*, 90 F.3d at 1582, 1584 n. 6). In addition to the specification, we must examine the prosecution history to determine whether the patentee relinquished claim coverage by amendment or through argument to overcome or distinguish a reference. *Id.* Although extrinsic evidence may be used by the court to help understand the disputed limitation, it may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history. *Vitronics*, 90 F.3d at 1584-85.

Novartis claims that the district court erred by not giving the term "lipophilic component" the broadest meaning possible. More specifically, Novartis asserts the district court unnecessarily added limitations concerning whether the "lipophilic component" may include surfactants and whether the constituents of the lipophilic component must be immiscible.

### A.

[12] Novartis begins its analysis by observing that "lipophilic" has a well-defined meaning to those skilled in the art. As defined by Novartis' expert, lipophilic means "fat- or oil-loving, or water hating." Novartis then notes that the specification teaches that:

The relative proportions will also vary, depending on the particular function of ingredients in the composition, for example, in the case of a surfactant component of a "microemulsion pre-concentrate", on whether this is employed as a surfactant only or both a surfactant and a co-solvent.

'840 patent, col. 16, ll. 36-41. Further, the specification teaches that:

When the surfactant comprises an effective solvent for the cyclosporin active ingredient, as in the case

e.g. of surfactants or mixtures of surfactants under (3.1.1.) to (3.2.7.) above, it may be incorporated into compositions as defined under (A), not only as surfactant, but in excess as an additional carrier or co-solvent phase, i.e. *as part of the hydrophilic or lipophilic phase*.

*Id.*, col. 12, ll. 44-49. Novartis claims that these teachings are inconsistent with the court's construction that a surfactant can form no part of the "lipophilic component." We agree with Novartis.

Claim 81 of the '840 patent recites a pharmaceutical composition that forms a microemulsion upon dilution by water. The composition comprises, in addition to the active ingredient, three other components. Namely, it contains (1) a hydrophilic component, (2) a "lipophilic component," and (3) a hydrophilic surfactant. Neither party cites any persuasive record evidence that the term "lipophilic component" (or "lipophilic phase component") had a well-defined meaning to those of ordinary skill in the art. Accordingly, the claim term requires that we turn to the intrinsic evidence, and if necessary, the extrinsic evidence, to elucidate the meaning that one skilled in the art would give the term. Johnson Worldwide, 175 F.3d at 990.

The passages of the specification quoted above indicate that a surfactant or a mixture of surfactants, provided it is an "effective solvent for the cyclosporin," may form, contrary to the district court's construction, a *part* of the lipophilic phase that dissolves the cyclosporin. Furthermore, the '840 patent discloses that if a surfactant forms a part of the lipophilic phase, it does so as a *co-solvent*. Col. 12, ll. 43-49, col. 16, ll. 36-41. A co-solvent is a "solvent that in conjunction with *another solvent* can dissolve a solute." *Webster's Third New International Dictionary* ("*Webster's* ") 514 (1993) (emphasis added). Novartis' \*1336 expert opines that the specification's disclosure indicates that a surfactant "could function *alone* " as the solvent in the lipophilic phase. (Emphasis added). By definition, however, a co-solvent operates with "another solvent" to dissolve a solute, such as cyclosporin. Novartis' expert testimony therefore directly contradicts the express teaching of the specification, and may not be used to give us appropriate guidance to reach the correct claim construction.

At oral argument, Novartis attempted to make a similar argument, asserting that the description of surfactants as making up only a "part" of the lipophilic phase, *see* '840 patent, col. 12, ll. 48-49, indicates that surfactants could constitute the whole

lipophilic phase. "Part," however, means "something less than a whole." *Webster's* at 1645. Because Novartis supplies insufficient record evidence to validate its unconventional interpretations of "co-solvent" and "part," as those words are used in the specification, Novartis' reading of the specification must be rejected.

In an attempt to further support its view that surfactants may constitute the entire lipophilic phase, Novartis notes that Example 4.1 in the '840 patent describes a "regular emulsion pre-concentrate" in which only a surfactant is used to dissolve the cyclosporin. The composition defined by claim 81 is not a regular emulsion pre-concentrate, however, but rather a microemulsion pre-concentrate, and therefore the example does nothing to advance our understanding of what composes the "lipophilic component" in the claimed composition. [FN4]

FN4. For the same reason, we must reject the assertion by Novartis' expert that the written description in the '840 patent at column 14, lines 39-44 provides further evidence that surfactants may form a part of the lipophilic component. The compositions as defined under (C) of the specification provide emulsion pre-concentrates and are directed to compositions "other than those as defined under (A) and (B)," (both of which are microemulsion pre-concentrates) to form "for example, solutions, suspensions, dispersion[,], regular emulsions and the like." '840 patent, col. 14, ll. 45-54.

Because the specification teaches that "*mixtures* of surfactants," if used to dissolve the cyclosporin, form only a "part" of the lipophilic phase, '840 patent, col. 12, ll. 43-49 (emphasis added), the other solvent forming the rest of the lipophilic phase must not be another surfactant. Rather, according to the specification, the remainder of the solvent constituting the lipophilic phase is a pharmaceutically acceptable non-surfactant lipophilic excipient that is capable of dissolving cyclosporin, such as those described under section (2) of the specification. *Id.*, col. 8, ll. 66-67; col. 9, ll. 5-46; col. 12, ll. 43-49. Accordingly, while we agree with Novartis that surfactants may form a part of the lipophilic component, the intrinsic record shows that this component cannot be composed entirely of surfactants, as urged by Novartis. Although Abbott initially argued in its opposition brief that the '840 patent "requires the lipophilic (phase) component to be comprised of an excipient other than a surfactant,"

Abbott later admitted in its cross-appeal brief and at oral argument that "a surfactant [may] contribute[ ] to the lipophilic phase so long as the lipophilic phase *also* contained at least one non-surfactant excipient." In view of the intrinsic evidence, the claimed "lipophilic component" must contain, at minimum, a pharmaceutically acceptable lipophilic substance capable of dissolving cyclosporin, and that is a non-surfactant excipient.

B.

[13] Novartis also challenges the district court's inclusion of the requirement that the lipophilic component must be immiscible \*1337 with the hydrophilic phase in the absence of surfactants. The specification states that "suitable components " for use in the lipophilic phase may include any pharmaceutically acceptable solvent that is non-miscible with the selected hydrophilic phase. '840 patent, col. 9, ll. 1-3 (emphasis added). The specification, contrary to the district court's reading, does not teach that the entire lipophilic phase must be immiscible with the hydrophilic phase, but rather only components, *e.g.*, parts, of the phase, in one embodiment, should be immiscible. We find nothing within the intrinsic record that compels reading the immiscibility limitation into the "lipophilic component" term.

III. Jury Verdict

Novartis asserts that even if we uphold the district court's construction of "lipophilic component," the jury's verdict on the '840 patent should be allowed to stand because there was substantial evidence for the jury to conclude that Abbott's cyclosporin composition infringed under the doctrine of equivalents. In granting JMOL, Novartis argues that the district court compounded the error of its claim construction by erroneously applying the specific exclusion principle and the all-elements rule. Moreover, Novartis suggests that even if we allow the claim construction to stand, the latter errors mandate a reversal of the JMOL.

In light of its exclusion of surfactants from the lipophilic component, the district court found that the specific exclusion principle precluded it, as a matter of law, from treating the surfactant as an element forming the lipophilic component. *Novartis*, 294 F.Supp.2d at 567. Left with no identifiable compound in the accused product corresponding to the lipophilic component, the district court held, under the all-elements rule, that no reasonable fact finder could conclude that Abbott infringes under the doctrine of equivalents. *Id.*

[14] As reviewed above in connection with claim construction, the specification informs us that the lipophilic component encompasses compositions that may include one or more surfactants, so long as the lipophilic component *also* contains at least one non-surfactant lipophilic excipient, which is capable of dissolving cyclosporin. Novartis argued that Span 80, which is a surfactant and an ingredient of the accused product, meets the lipophilic component limitation under the doctrine of equivalents. Novartis cites the testimony of its expert who opined at trial that Span 80 "*does not* exhibit the amphiphilic function of a surfactant" nor does it "*function* as a surfactant ... but, rather, that it *functions* as the lipophilic component." (Emphases added). The fact that Span 80 may "function" as a co-solvent to cyclosporin does not answer, however, whether a suitable non-surfactant excipient is also present in the accused composition, thereby bringing the alleged co-solvent mixture within the scope of the term "lipophilic component," either literally or under the doctrine of equivalents.

In light of the specification's implicit teaching that surfactants do not compose the entire portion of the lipophilic component, Novartis is foreclosed from arguing that Span 80, which the specification expressly acknowledges is a surfactant, '840 patent, col. 9, ll. 49-50; col. 11, ll. 58-62, is an equivalent to a pharmaceutically acceptable *non-surfactant* lipophilic excipient, as required by the lipophilic phase under our claim construction. See *SciMed Life Sys., Inc. v. Advanced Cardiovascular*, 242 F.3d 1337, 1347 (Fed.Cir.2001) ("[I]f a patent states that the claimed device must be 'non-metallic,' the patentee cannot assert the patent against a metallic device on the ground that a metallic device is equivalent to a non-metallic device."); *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1305 (Fed.Cir.2001) ("A finding of equivalence \*1338 [with Sylvania's AlO(OH) and Al(OH)<sub>3</sub> coatings] would vitiate the limitation 'oxide coating,' which we have concluded is defined to primarily consist of a binary compound."); see also *Athletic Alternatives, Inc. v. Prince Mfg. Inc.*, 73 F.3d 1573, 1582 (Fed.Cir.1996) ("As a corollary to the 'all limitations' rule ..., we have held that 'the concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims.' " (citation omitted)).

Novartis claims that the district court's holding that Span 80 may not, as a matter of law, be regarded as an equivalent to a non-surfactant excipient under the



asserted patents is contrary to the Supreme Court's decision in Graver Tank & Manufacturing Co. v. Linde Air Products Co., 339 U.S. 605, 70 S.Ct. 854, 94 L.Ed. 1097 (1950), and this court's decision in Wright Medical Technology, Inc. v. Osteonics Corp., 122 F.3d 1440 (Fed.Cir.1997). We disagree. In *Graver Tank*, the patentees asserted four claims directed to welding flux made of alkaline earth metal silicates. 339 U.S. at 607, 70 S.Ct. 854. Except for the type of metal silicate present, the accused product was alike in all respects to the claimed welding flux. *Id.* at 610, 70 S.Ct. 854. The parties disputed whether silicates made of manganese metal in the accused product could be treated as an equivalent to silicates made of alkaline earth metal. *Id.* The Court found that the difference between the metal silicates was insubstantial, and they therefore could be considered equivalents. *Id.* Notably, there was no dispute that the metal silicate element was present in the accused product. Rather, the dispute focused on a limitation of the metal silicate element.

Similarly, in *Wright Medical*, there was no dispute that the accused product employed intramedullary rod elements, just as in the claimed invention. 122 F.3d at 1445. The asserted independent claim defined a femoral surface shaping guide comprising "an intramedullary rod portion adapted to *closely fit in and extend through* the narrowest portion of the human femur." *Id.* at 1442 (emphases added). The district court construed "closely fit" to mean "a tight or snug fit between the rod and the isthmus of the femur" and "extend through" to require that the "rod pass through the entire length of isthmus." *Id.* at 1444. Under this claim construction, the parties agreed that the intramedullary rods of the accused product did not fit tightly against or extend through the isthmus of the femur, and thus the product did not literally infringe the asserted patent. *Id.* The parties disputed, however, whether the rods in the accused product were insubstantially different from that claimed, and thus, whether the accused product infringed under the doctrine of equivalents. *Id.* at 1445. The district court granted summary judgment to the accused infringer, rejecting the patentee's theory for infringement by equivalence because the theory "attempt[ed] to ignore claim limitations on which the public is entitled to rely." *Id.* We found that summary judgment for the accused infringement was improper, and held that the fact finder must be given the opportunity to determine whether the intramedullary rod in the accused product is equivalent to that used in the claimed invention. *Id.* at 1446.

In both *Graver Tank* and *Wright Medical*, the fact that certain claimed limitations in the element at issue were missing in the accused product did not change the fact that the element, albeit different from that expressly claimed, was indeed present in the accused product. In *Graver Tank*, for instance, although the accused product used manganese metal instead of an alkaline earth metal, that substitution did not transform the disputed element, i.e., metal silicate, into something that was not a metal silicate. Similarly, in *Wright Medical*, \*1339 although the intramedullary rod in the accused product did not tightly fit and extend through the isthmus of the femur, as required by the literal claim language, the absence of those claimed limitations did not vitiate the fact that the accused product possessed an "intramedullary rod."

[15] When the substitution of one feature, however, for another into an element of the accused product places it outside the scope of the recited claim element, the doctrine of equivalents may not be applied. Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed.Cir.1997); see, e.g., Durel Corp., 256 F.3d at 1305 (finding that the addition of hydroxyl groups to the alleged oxide coating in the accused product made it no longer an "oxide coating" as properly construed under the asserted patent, and thus placing the accused product outside the reach of the doctrine of equivalents). Permitting such an element in the accused product to come within the bounds of the claimed element would impermissibly extend the scope of the claim language beyond what the patentee actually claimed.

Here, the "lipophilic component" element requires at least a pharmaceutically acceptable non-surfactant lipophilic excipient capable of dissolving cyclosporin. Under Novartis' theory of infringement by equivalence, Span 80, admittedly a surfactant according to the '840 patent, see col. 9, ll. 47-50, col. 11, ll. 58-59, is an equivalent to the *non-surfactant* excipient required by the claimed "lipophilic component." Including a chemical composition made entirely of surfactants within the scope of "lipophilic component" would be inconsistent with the claim construction of that term. We must reject Novartis' theory of infringement by equivalence. Because Novartis failed to adduce evidence from which a reasonable juror could conclude, consistent with this court's claim construction, that there is a "lipophilic component" in Abbott's accused product, we find no basis to reverse the JMOL for noninfringement of the '840 patent.

#### IV. Cross-Appeal

In Abbott's conditional cross-appeal, it claims that in the event we reverse the JMOL, we should not reinstate the jury verdict. Rather, Abbott urges this court to grant it a new trial on the '840 patent, because the jury verdict of infringement of the '840 patent is irreconcilably inconsistent with the jury verdict of noninfringement as to the '625 patent. In addition to the inconsistency, Abbott contends that it is entitled to a new trial on the '840 patent because the jury's verdict is contrary to the clear weight of the evidence and because the district court erroneously excluded evidence that Abbott holds its own patents for its accused product.

[16][17] The district court granted Abbott's motion for JMOL for noninfringement and denied Abbott's alternative motion for a new trial as moot. *Novartis*, 294 F.Supp.2d at 560. "[A] party who prevails on noninfringement has no right to file a 'conditional' cross-appeal to introduce new argument or challenge a claim construction, but may simply assert alternative grounds in the record for affirming the judgment." *Phillips v. AWH Corp.*, 363 F.3d 1207, 1216 (Fed.Cir.2004). "It is only necessary and appropriate to file a cross-appeal when a party seeks to enlarge its own rights under the judgment or to lessen the rights of its adversary under the judgment." *Bailey v. Dart Container Corp. of Mich.*, 292 F.3d 1360, 1362 (Fed.Cir.2002). The conditional cross-appeal is dismissed as improper because the district court entered a judgment of noninfringement in Abbott's favor. See *Phillips*, 363 F.3d at 1216.

#### CONCLUSION

Although the district court's claim construction was erroneous, we find, under \*1340 our amended claim construction, no error in the district court's grant of the JMOL. We reverse the claim construction but affirm the grant of JMOL for noninfringement on claim 81 of the '840 patent.

**AFFIRMED.**

BRYSON, Circuit Judge, dissenting.

Claim 81 of the '840 patent recites a composition comprising four components: cyclosporin A; a propylene glycol hydrophilic component; a hydrophilic surfactant; and a lipophilic component. The lipophilic component is described in the patent as an oil-loving substance that dissolves the cyclosporin so that when water is added to the composition an oil-in-water microemulsion is created.

It is not disputed that the accused Abbott composition contains the first three of the claimed components; only the presence of a lipophilic component is in dispute. Novartis argues that the Abbott composition has a lipophilic component in the form of Span 80, a lipophilic surfactant. Abbott argues that although Span 80 is lipophilic, it cannot serve as the lipophilic component of claim 81. The court today agrees with Abbott, based on statements in the specification of the '840 patent. Although the court acknowledges that a lipophilic surfactant such as Span 80 can serve as *part* of the claimed lipophilic component, it holds that the specification does not allow for a surfactant to serve as the *entire* lipophilic component. Accordingly, the court holds that because Span 80 is the only lipophilic component in Abbott's composition, the Abbott composition does not infringe, either literally or under the doctrine of equivalents.

Because it is undisputed that Span 80 is lipophilic and that cyclosporin dissolves in Span 80, Span 80 appears to qualify as a "lipophilic component" as that term is used in the '840 patent. Thus, Abbott can prevail on this claim construction issue only if the specification is read as requiring that the "lipophilic component" limitation be construed more narrowly. The court today concludes that the specification has that effect, but I do not agree.

In reaching its conclusion as to the proper construction of the term "lipophilic component," the court relies on a passage from the specification stating that a surfactant may be incorporated in a microemulsion composition of the invention not only as the surfactant, "but in excess as an additional carrier or co-solvent phase, i.e. as part of the hydrophilic or lipophilic phase." '840 patent, col. 12, ll. 47-49. See also *id.*, col. 14, ll. 40-42 (referring to a lipophilic surfactant serving "as a surfactant or as a co-solvent"); *id.*, col. 16, ll. 39-41 (referring to a surfactant that is "employed as a surfactant only or both a surfactant and a co-solvent"). The court interprets that language, which recognizes that a surfactant can serve as part of the hydrophilic or lipophilic components of the claimed composition, as meaning that a surfactant may be a part of the lipophilic component but may not serve as the lipophilic component by itself.

I do not draw the same conclusion from the quoted language. The statement on which the court relies refers to the role performed by excess amounts of the substance that serves the role of the surfactant in the

claimed composition. The quoted language indicates that the composition of the invention must have at least three components in addition to the cyclosporin, as required by claim 81. In addition, it contemplates that the substance that serves as the surfactant may also serve as part of either the hydrophilic or the lipophilic component. The quoted language therefore makes clear that the composition may not consist of only two components \*1341 in addition to the cyclosporin, as would be the case if one ingredient served as both the surfactant and the lipophilic component in the composition. However, the quoted language does not address the case presented by Abbott's composition, which contains three components in addition to the cyclosporin, and in which a hydrophilic surfactant serves as the surfactant, while Span 80 serves the function of the lipophilic component (dissolving and carrying the cyclosporin). Thus, because in Abbott's composition Span 80 does not serve as the surfactant referred to in claim 81, the quoted language from the specification does not apply to Abbott's composition. For that reason, I agree with Novartis that, where another substance serves as the hydrophilic surfactant, the specification does not disclaim the use of a lipophilic surfactant such as Span 80 as the sole component of the lipophilic component of the claimed invention. I therefore do not find a disclaimer of subject matter in the specification. *A fortiori*, I do not find a specific exclusion of subject matter for purposes of the doctrine of equivalents.

I respectfully dissent.

375 F.3d 1328, 71 U.S.P.Q.2d 1650

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